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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/706,325	11/03/2000	Juan M. Zapata	P-LJ 4453	6212

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 05/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/706,325

Applicant(s)
Zapata et al

Examiner
Karen Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above, claim(s) 1-7, 12-45, and 47-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-11, 46, and 68-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6, 7
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

1. Acknowledgment is made of applicants election with traverse of Group III, drawn to anti-TPBD antibodies, cell lines producing said antibodies and TPBD-modulating agents. The traversal is on the grounds that examination of Group II will result in a coextensive search for the subject matter of Group V, drawn to methods of using the antibody of Group III. This has been considered but not found persuasive. Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group II can also be used in the different methods of Groups V and VI. As to the question of burden of search, the claims of Groups II and V are classified differently, necessitating different searches in the U.S. Patent shoes. Further, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Clearly different searches and issues are involved in the examination of each group.

However, the policies set forth in the Commissioner's Notice of February 28, 1996 published on March 26, 1996 at 1184 O.G. 86 will be followed. Method claims limited to the scope of the allowable product claims will be rejoined and examined at the time the product claims are indicated as being allowable.

For these reasons the restriction requirement is deemed to be proper and is adhered to. The requirement is therefore made FINAL.

2. Claims 1-73 are pending. Claims 1-7, 12-45 and 47-67, drawn to non-elected inventions, are withdrawn from consideration. Claims 8-11, 46 in part, and 68-73 are examined on the merits.

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Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 68-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 68 and 69 recite “an effective agent” without defining how to measure an “effective agent” versus an ineffective agent.

Claims 68, 72 and 73 recite “association of TPBD with a TNF family receptor or a TRAF protein, TRAF protein or a TRAF-associated protein. It is unclear if the agent is to modulate or inhibit the association with TRAF protein and TRAF associated protein apart from TPBD as TRAF protein is repeated twice.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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6. Claims 8, 9, 46 and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by Inoue (WO 97/38099). Claim 8 is drawn to an isolated anti-TPBD antibody. Claim 9 specifically embodies a monoclonal antibody. Claim 46 is drawn to a therapeutic composition comprising an anti-TPBD antibody and a pharmaceutically acceptable carrier. Claim 68 is drawn to an agent which binds a Traf protein binding site of TPBD. Inoue discloses monoclonal antibodies which bind the separate domains of Traf5 which include C-Traf. The instant specification teaches that TPBD of the instant invention corresponds to C-Traf (page 9, lines 3-5). Therefore, the anti-C-Traf antibodies taught by Inoue are the same as the claimed anti-TPBD antibodies and the claimed agent which binds a the TPBD of Traf5. Inoue et al disclose that the monoclonal antibodies which bind Traf5 or its parts are useful in the treatment of allergies and in cell proliferation inhibition, therefore a therapeutic composition comprising the claimed antibodies is disclosed by Inoue.

7. Claims 8, 11 and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagai et al (FEBS Letters, 1997, Vol. 418, pp. 23-26, paper of the IDS filed May 15, 2001). Claim 8 is drawn to an isolated anti-TPBD antibody. Claim 11 specifically embodies polyclonal antibodies. Nagai et al discloses anti-serum from a patient reactive with the C-terminal peptide of SPOP. Claim 68 is drawn to an agent which binds a Traf protein binding site of TPBD. SPOP comprises SEQ ID NO:19 at the C-terminus, therefore the TPBD is at the C-terminus and the polyclonal antibodies of the patient anti-serum bind TPBD of SPOP.

8. Claims 68, 69, 71 and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Rothe et al (PNAS, 1996, Vol. 93, pp. 8241-8246, paper of the IDS filed May 15, 2001). Claim 68 is drawn to an agent which binds a Traf protein binding site of TPBD. Claim 69 is drawn to an agent which modulates the association of TPBD with a TNF receptor or a Traf protein. Claim 72 embodies inhibiting the association between TPBD and a Traf protein.

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Rothe et al disclose I-Traf which binds to the Traf-C domain of Traf1 and inhibits the association of the Traf-C domain of Traf2 to Traf1. As the Traf-C domain is the same as the TPBD domain, for the reasons set forth in paragraph 6 above, Rothe et al meets all the embodiments of claims 68, 69, 71 and 72.

9. Claims 68, 69 and 73 are rejected under 35 U.S.C. 102(a) as being anticipated by MacLachlan et al (Journal of Cellular Biochemistry, 1998, Vol. 71, pp. 467-478). Claim 68 is drawn to an agent which binds a Traf protein binding site of TPBD. Claim 69 is drawn to an agent which modulates the association of TPBD with a Traf-associated protein. Claim 73 embodies claim 69, wherein the modulation is an increase in the association of TPBD with a Traf-associated protein.

MacLachlan et al disclose CDK9, a Traf-associated protein which interacts with Traf2 through the WKI motif present in the C-terminus of Traf2. Thus, CDK9 binds the TPBD site of Traf2. MacLachlan et al disclose that Traf2 acts as a scaffold for the recruitment of CDK9 and other Traf-associated factors to solidify the complex or direct CDK9 to substrates.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to

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the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 8, 9, 10 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lelias et al (US 5,705,615) in view of Young et al (US 6,346,605). Claim 8 is drawn to an isolated anti-TPBD antibody. Claims 9 and 10 specifically embody a monoclonal antibody and a cell line producing said antibody. Claim 46 is drawn to a therapeutic composition comprising an anti-TPBD antibody and a pharmaceutically acceptable carrier. Claim 68 is drawn to an agent which binds a Traf protein binding site of TPBD.

Lelias et al teach a pharmaceutical composition of antibodies which bind to Traf-1, 2, and 3 useful for blocking Traf-1, 2 and 3 from binding to the TNF-receptor. Lelias et al does not specifically teach that said antibodies bind to the TPBD of the corresponding Traf proteins.

Young et al teach that Traf interacts with the TNF-receptor through the C-Traf domain, which is the same as the TPBD, for the reasons stated in paragraph 6, above.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to make antibodies which specifically bind to the Traf-c domains of Traf-1, 2 and 3 for the blocking of Traf-1, 2 and 3 from the TNF-receptor. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Young et al on the association of the Traf-C domains of Traf proteins with the TNF-receptor.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may

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be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

May 6, 2002


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